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(71) Applicant (*for all designated States except US*): THE QUEEN'S UNIVERSITY OF BELFAST [GB/GB]; 8 Malone Road, Belfast BT9 5BN (GB).

(72) Inventor; and
(75) Inventor/Applicant (*for US only*): GILLAN, Mark [GB/GB]; 46 Church Road, Ballynahinch, County Down BT24 8LP (GB).

(74) Agent: MURGITROYD & COMPANY; 373 Scotland Street, Glasgow G5 8QA (GB).

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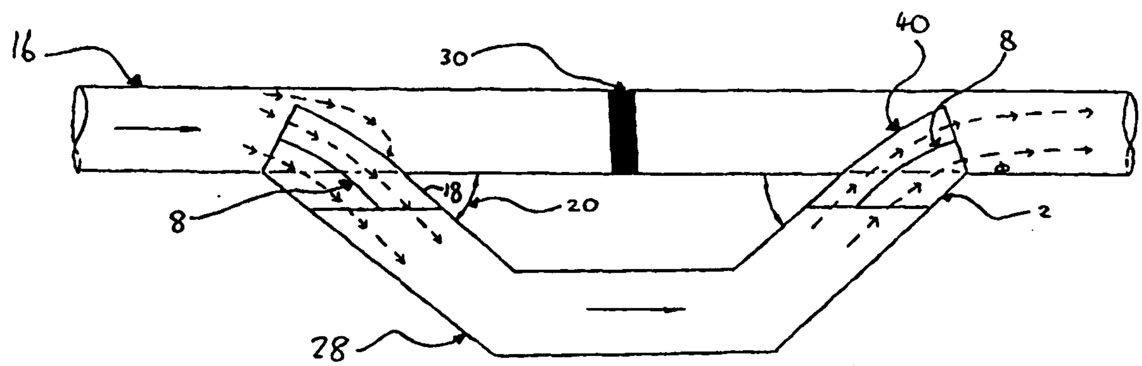

(57) Abstract

The present invention provides a graft haemodynamic control device suitable for reducing anastomotic intimal hyperplasia, comprising a cylindrical body, optionally with control vanes therein, which connects an artery to a bypass graft and which controls the flow of blood therebetween. The device is made of any compliant material, usually a plastic material such as PTFE, Dacron or Goretex and coated with Teflon. The device is less compliant than the graft. It may be attached to the artery and the graft by recognised techniques.

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"Haemodynamic Control Device"

The invention relates to the surgical procedure of using biological or synthetic grafts to bypass occluded or severely stenosed arteries. Intimal hyperplasia in the vicinity of the vascular anastomoses is a primary factor in the medium and long-term failure of grafts. This invention is a haemodynamic control device which judiciously adapts the local flow field, by reducing both the spatial shear stress gradients and the extent of long particle residence times in the vicinity of an anastomosis, thereby reducing the likelihood of intimal hyperplasia and the subsequent failure of the graft.

In this field it is already known that

1. Anastomotic intimal hyperplasia is a common cause of post-operative vascular graft failure, especially for synthetic grafts.

2. In addition to graft/artery compliance mismatch the other primary mechanism which is universally acknowledged to promote intimal hyperplasia is adverse haemodynamic flow patterns in the vicinity of the anastomosis.

3. The most common regions exhibiting intimal hyperplasia are around the suture line, at the heel and toe of the anastomosis and along the floor opposite the anastomosis (see Figure 3).

4. Development of intimal hyperplasia is more prevalent at the distal anastomosis than at the proximal anastomosis.

5. There is a direct relationship between the localities of intimal hyperplasia and the anastomotic surface which are experiencing low shear and long particle residence times.

6. High spatial wall shear stress gradients promote intimal hyperplasia.

7. The anastomotic graft angle is of fundamental importance to defining the wall shear stress: a shallow or small anastomotic angle results in a decreased region of separated flow which reduces the likelihood of intimal hyperplasia.

8. The anastomotic angle is limited both by the graft material and the mechanics of suturing/skill of the surgeon.

The types of vascular patients that the surgeons treat fall principally into three groups:

Group 1 - Normal Vascular Patients:

Typically these patients have atherosclerosis, viz a disease process affecting the wall of arteries and in this group it involves the main arteries of the tummy and thigh extending to about knee level. Essentially

this is a process in which yellow fatty plaques build up eccentrically in the arterial wall in different locations. This proceeds at a rate depending on certain critical stimuli, to cause occlusion of the artery. As the plaque develops a varying degree of calcium forms in it causing a varying degree of hardness producing a softish thick walled artery to an artery which will not accept a needle.

The plaque undergoes a degree of necrosis and blood then clots on it causing complete occlusion, this is a thrombus and it propagates proximally i.e. upstream to the next main branch of the vessel where it stops. The vessels of the calf are only ever mildly affected.

Group 2 - The Diabetic Vascular Patient:

This patient often has a degree of disease distribution as described above though usually the thigh artery is affected. However this group has the disease always in the three vessels of the calf, the tibial arteries and they are in parallel. They may be hard but principally have concentric layers of atheroma building to cause skip like areas of narrowing and occlusion. Even these are amenable to bypass. But in the diabetic the real problem are the arterioles, the tiny little vessels that bleed when you cut yourself shaving. These are narrowed by the building up of hyaline, a tough scar like material. Again the arterioles are considered to be in parallel hence further increase in peripheral resistance.

Group 3 - The Renal Vascular Patient:

The kidney patient relies frequently on dialysis and is often Diabetic. This group tends to have a very poor

prognosis for in addition to the common features of the Group's 1 and 2 their vessels are remarkably hard even early in life. On the other hand the wall may be very soft but mushy and thick. Their prognosis is determined too by the state of the arterioles and as yet unrecognised biochemical abnormalities relating to the primary renal pathology.

There is also an interesting but relatively rare group of patients who suffer from thrombophilia which is essentially the opposite of haemophilia where the patient has a disorder of the haemopoietic system in which there is a tendency for thrombosis to occur.

Currently all present research into this field appears to be cited around optimising the graft material and not controlling the flow at the anastomoses.

However, this has the disadvantage that, without haemodynamic control at the distal, and to a lesser extent at the proximal anastomosis one will always incur high spatial shear stress gradients in the vicinity of the anastomotic junction and therefore intimal hyperplasia.

In the medium to long-term, the graft will eventually fail, thus necessitating a new surgical bypass procedure with all the additional risks which it entails.

According to the present invention there is provided a graft haemodynamic control device suitable for reducing anastomotic intimal hyperplasia, the device comprising a substantially cylindrical body wherein one end is capable of being attached to a bypass graft and the other end capable of being positioned in an artery such

that the device connects the graft and the artery and controls the flow of blood there between.

The device may be manufactured from the same compliant material as the graft but will be less compliant.

The device may be of one piece construction.

The device may be manufactured in a variety of sizes and options to match the chosen graft/host artery's architecture.

In one embodiment the device is configured to be a proximal control device controlling flow from an artery to a graft.

In an alternative embodiment the device is configured to be a distal control device to control flow of blood from graft into artery.

The invention may further comprise a kit including proximal and distal haemodynamic control devices.

In one embodiment the device comprises at least one control vane such that flow is directed between the artery and graft to decrease spatial shear stress gradients and long particle residence times in the vicinity of anastomoses.

More preferably the device comprises at least one control valve such that flow is directed between the artery and graft to decrease spatial shear stress gradients when used in larger diameter host arteries. Larger diameter host arteries are defined as having a bore of greater than 6 mm.

In one embodiment the control vane divides the body of the device into two separate chambers.

Suitably the device may be manufactured from any compliant material.

Preferably the device is coated with teflon or a similar material.

Preferably also the device is manufactured from any one or any mixture of the group consisting of PTFE, Dacron or Goretex.

Suitably the device may be attached to grafts using established methodology such as suturing or biological glues.

The shape and dimensions of the device will differ depending on the size of the host artery and graft and on whether it is to be attached at the proximal or distal ends of the graft.

In a preferred embodiment the device comprises a peripheral collector, which may comprise a thin compliant porous area, to enhance flow vectoring into the graft.

The invention can further comprise a peripheral ejector, which may comprise a thin compliant porous area, in the device to enhance flow vectoring into the host artery.

Suitably the device can further comprise secondary control vanes to enhance flow vectoring into and out of larger diameter grafts.

Most preferably the device can further comprise secondary control vanes to enhance flow vectoring into and out of larger diameter grafts (diameters greater than 1 cm).

The diameter of the device according to the invention can range from 2mm to 1.5cm depending on the size of the grafts and the host arteries being connected.

Typically a device according to the present invention is of a synthetic one-piece construction and incorporates a primary control vane and a periphery collector or ejector.

The device may include constant angle guidelines to assist attachment to the graft at optimum anastomotic angle.

The invention further provides a kit comprising a synthetic graft and proximal and distal haemodynamic control devices.

Suitably one end is unattached to allow the other end to be cut to size.

The invention also provides preattached or integral haemodynamic control devices on synthetic grafts.

The present invention will now be further described by way of example with reference to the accompanying drawings, in which:

Figure 1 is a front view of the haemodynamic flow control device, taken along a cross section, showing a schematic enlargement of a haemodynamic control device for proximal side-to-end anastomosis.

Figure 2 is a front view of the haemodynamic flow control device of Fig. 1, taken along a cross section, showing the schematic haemodynamic flow pattern for an occluded bypass graft with the haemodynamic flow control device of the present invention fitted at both the proximal and distal anastomoses;

Figure 3 shows the schematic haemodynamic flow pattern for an occluded bypass graft with regions of intimal hyperplasia in the vicinity of the distal end-to-side anastomosis;

The haemodynamic flow control device as shown in Figures 1 and 2 is formed from a single piece of plastic material 2, which is shaped to form a cylindrical body 4. The bore 6 of cylindrical body 4 is divided into two by control vane 8 and is further divided into four by parallel secondary control vanes 10 and 12. Control vanes 8, 10 and 12 run along the longditudal axis of cylindrical body 4. The rim 14 of cylindrical body 4, designed to be sutured into the host artery 16 has an overlap flap 18 running the outside of the cylindrical body 4 at anastomotic angle 20 from one edge of the rim 14. The area of the cylindrical body 4, above the overlap flap 18 is porous. Also running around the edge of the cylindrical body 4 at the end designed to be attached to the graft and at the anastomotic angle 20, are a series of incisions 22, 24 and 26 spaced equidistantly, as graft attachment guidelines (synthetic grafts only).

In use the haemodynamic flow device (2) is attached to host artery 16 at anastomotic angle 20 by virtue of overlap flap 18, by conventional methods and is attached to graft 28 in order to bypass occlusion 30. Use of the flow control device helps to prevent effects

shown in figure 3 such as undesirable flow effects 32 and 34 and helps to prevent intimal hyperplasia build ups 36, 38 and 40.

This invention is a novel vascular graft haemodynamic control device (HCD) which can be attached at either, or both, the proximal and distal anastomotic junctions. The HCD judiciously adapts the local flow field, by decreasing both the spatial shear stress gradients and the extent of long particle residence times in the vicinity of an anastomosis, thereby reducing the likelihood of intimal hyperplasia and the subsequent long-term failure of the graft.

HCD Design

The HCD is of a synthetic one-piece construction and can optionally incorporate a primary control vane (8) with optional secondary control vanes (10,12) and an optional periphery collector/ejector. Fig 2 shows a typical vascular bypass graft with two HCD's attached at both the proximal and distal anastomoses. Both of the HCD's depicted in Fig 2 contain a primary control vane and the optional periphery collector/ejector. The HCD is manufactured in a variety of sizes and options to match the chosen graft/host arteries' architecture.

Primary Control Vane

The primary control vane (8) (see Fig 1) is a thin compliant haemodynamic flow vectoring control surface. The length, axial location and variable pitch of the primary control vane is optimised for the HCD size, locality (i.e. proximal or distal) and the elasticity of the host artery.

Optional Secondary Control Vanes

The optional secondary control vanes (10,12) (see Fig 1) are thin compliant haemodynamic flow control surfaces which are utilised to enhance flow vectoring into and out of the larger diameter grafts. The length, axial location and variable pitch of these control vanes are once again optimised for the HCD size, locality (i.e. proximal or distal) and elasticity of the host artery.

Optional Periphery Collector/Ejector

The optional periphery collector/ejector (40) (see Fig 2) is a thin compliant porous haemodynamic collector or ejector device depending on whether the HCD is at the proximal or distal anastomosis respectively. The length, porosity and variable pitch of the periphery collector/ejector is dependant on the primary control vane dimensions, the locality (i.e. proximal or distal) and elasticity of the host artery. The periphery collector/ejector is utilised to enhance flow vectoring and to reduce the extent of long particle residence times fore and aft of the occlusion.

Surgical HCD Attachment Procedure

The HCD may be attached (during the surgical procedure) to existing synthetic or biological grafts using a variety of established methodologies, including suturing and biological glues. The HCD is attached to the graft in a manner which allows a small overlap of graft material to remain above the attachment point thereby enabling the surgeon to suture and/or bond the graft onto the artery as normal (see Fig 2). As depicted in Fig 2 the HCD synthetic graft attachment

procedure can be made more straightforward by the addition of constant angle guide-lines (22,24,26) along the length of the graft thus ensuring that the surgeon attaches the graft and HCD at the optimum anastomotic angle. (Note: pre-attached (or integral) HCDs on the proximal end of synthetic grafts can be employed to simplify/expedite some of the more uncomplicated surgical bypass procedures).

The advantages of the invention and/or the ways in which the disadvantages of previously known arrangements are overcome, include:

Procedural:

1. The haemodynamic control device judiciously adapts both the proximal and distal anastomotic graft flow-patterns thereby reducing both local spatial shear stress gradients and the extent of long particle residence times thus decreasing the likelihood of intimal hyperplasia in the vicinities of the heel, toe and floor regions (see Fig 3).

2. The associated increase in the medium to long-term patency of the graft anastomoses enhances the patient's survival rate.

3. The graft/control device attachment procedure is relatively straightforward and the associated synthetic graft suturing guide-lines ensure that the surgeon attaches the graft at the optimum anastomotic angle.

4. The control device may also be utilised in biological grafts.

Fiscal:

1. The control device can be attached to existing grafts.

2. Enhanced medium to long-term patency reduces the need to perform expensive staff intensive re-operative procedures which are statistically less successful than the original procedure.

Claims

1. A haemodynamic control device suitable for reducing anastomotic intimal hyperplasia, the device comprising a substantially cylindrical body wherein one end is capable of being attached to a bypass graft and the other end capable of being positioned in an artery such that the device connects the graft on the artery and controls the flow of blood there between.

2. A haemodynamic control device as claimed in Claim 1, which is configured to be a proximal control device controlling flow from an artery to a graft.

3. A haemodynamic control device as claimed in Claims 1 or 2 which is configured to be a distal control device to control flow of blood from graft into artery.

4. A haemodynamic control device as claimed in Claims 1, 2 or 3, which comprises a least one longitudinal control vane.

5. A haemodynamic control device as claimed in Claim 4 wherein the control vane divides the body of the device into two separate chambers.

6. A haemodynamic control device as claimed in any preceding Claim which is manufactured from a compliant material.

7. A graft haemodynamic control device as claimed in Claim 6 wherein the compliant material is less compliant than the material of the graft.

8. A haemodynamic control device as claimed in any preceding Claim, which is manufactured from any one or any mixture of the group consisting of PTFE, Dacron or Goretex.

9. A haemodynamic control device as claimed in any preceding Claim which is coated with a Teflon type material.

10. A haemodynamic control device as claimed in any preceding Claim, which is attachable to grafts using established methodology such as suturing or biological glues.

11. A haemodynamic control device as claimed in any of Claims 1, 2 and 4 to 10 comprising a peripheral collector, which may comprise a thin compliant porous area, to enhance flow vectoring into the graft.

12. A haemodynamic control device as claimed in any of Claims 1 and 3 to 10 which further comprises a peripherally ejector, which may comprise a thin compliant porous area, in the device to enhance flow vectoring into the host artery.

13. A haemodynamic control device as claimed in any preceding Claim which further comprises secondary control vanes to enhance flow vectoring into or out of an outer large diameter graft.

14. A kit comprising at least one proximal haemodynamic control device and at least one distal haemodynamic control device.

15. A synthetic graft including a haemodynamic control

device as claimed in any of the preceding Claims.

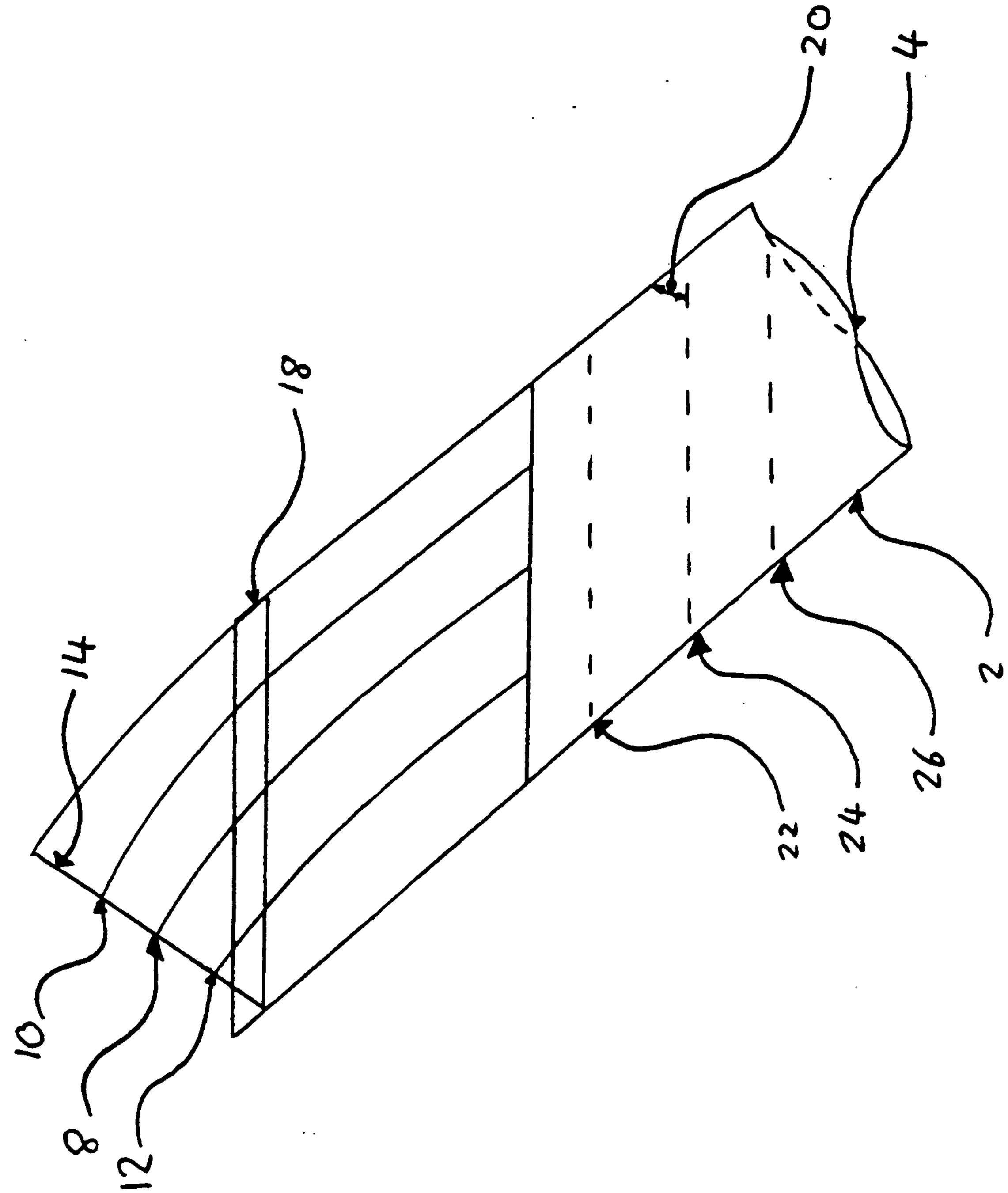

Figure 1
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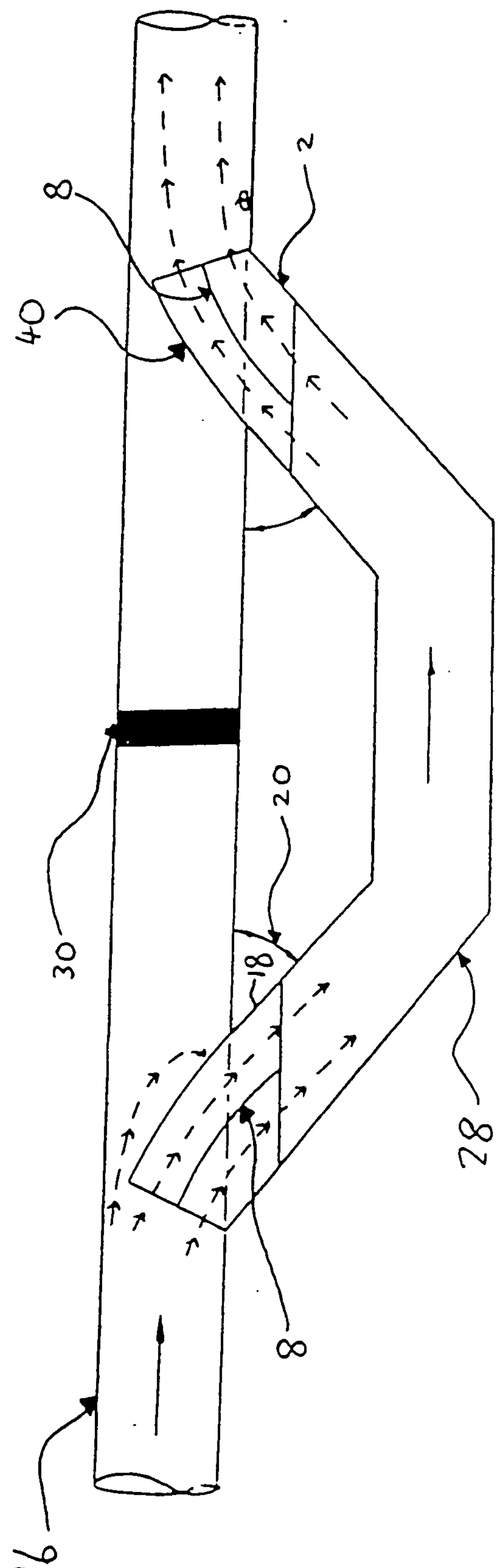

Figure 2

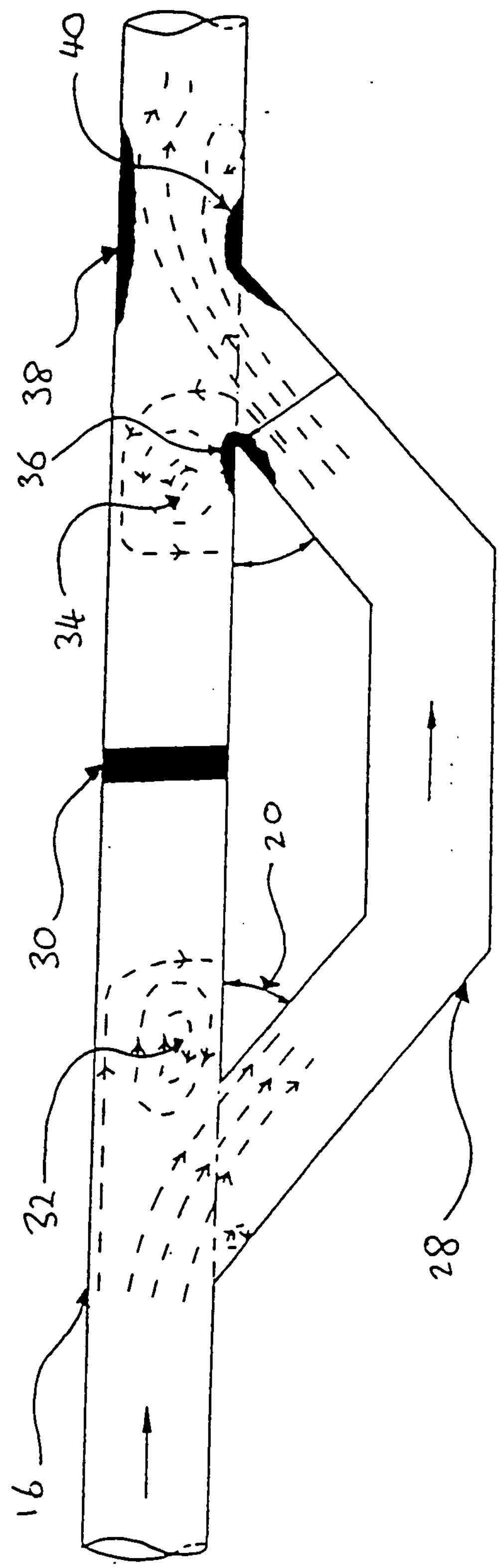

Figure 3

International Application No
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A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06 A61B17/11

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F A61B A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 503 568 A (MADRAS) 12 March 1985 see the whole document	1,14,15
A	US 3 882 862 A (BERENDT) 13 May 1975	
A	US 3 818 511 A (GOLDBERG ET AL) 25 June 1974	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 4503568	A	12-03-1985	NONE	
US 3882862	A	13-05-1975	NONE	
US 3818511	A	25-06-1974	NONE	